



Vaccine Administration Errors and Deviations

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Interim recommendations for vaccine administration errors and deviations are summarized in the table below.

Table 7. Interim recommendations for JYNNEOS vaccine administration errors and deviations

Туре	Administration error/deviation	Interim Recommendation
Site	Incorrect site (e.g., a site other than triceps area for subcutaneous administrations or a site other than the volar aspect of forearm for intradermal administrations)	Do not repeat dose. Inform the recipient of the potential for local and systemic adverse events.
Route	Incorrect route resulting in lower-than-authorized dose administered (e.g., inadvertent subcutaneous administration of 0.1 mL, when intradermal route was intended).	Repeat dose immediately via intended route (no minimum interval).
Route	Other incorrect route (e.g., intramuscular administration).	Do not repeat dose. Inform the recipient of the potential for local and systemic adverse events.
Dosage	If the incorrect dosage is administered, resulting in a higher-than-authorized dose (e.g., >0.1 mL administered ID).	Do not repeat dose. Inform the recipient of the potential for local and systemic adverse events.
Dosage	If the incorrect dosage is administered, resulting in a lower-than-authorized dose (e.g., recipient pulled away, leaked out of a syringe, 0.1 mL administered subcutaneously).	Repeat dose immediately (no minimum interval). However, if a half-volume dose of vaccine is administered to a patient instead of the intended full volume, another half-volume dose can be administered on the same clinic day, and the 2 halves can count as 1 full dose.

Intervals	Interval between first and second dose less than the recommended minimum interval. ¹	Repeat dose after the dose given in error by at least the recommended interval of 28 days if the patient is severely immunosuppressed. ² Otherwise, do not repeat dose. ¹
Intervals	Interval between first and second dose greater than the recommended minimum interval.	Do not restart the series and administer the second dose as soon as possible. While available clinical data show that the second dose may be given up to 7 days after the minimum interval of 28 days (i.e., 35 days after the first dose), there is no maximum interval and the second dose should be given as soon as possible to complete the series.
Storage and handling	Dose administered after improper storage and handling (i.e., temperature excursion)	Contact the manufacturer3 for information on the stability of the vaccine. If the manufacturer does not have data to support the stability of the vaccine, repeat the dose immediately (no minimum interval).
Storage and handling	Dose administered past the expiration/beyond-use date	Contact the manufacturer3 for information on the stability of the vaccine. If the manufacturer does not have data to support the stability of the vaccine, repeat the dose immediately (no minimum interval).

¹Vaccine doses administered up to 4 days before the minimum interval may be counted and do not need to be repeated. ²Contact information for manufacturer:

 $Email: medical.information_US@bavarian-nordic.com\\$

U.S. phone number: 1-844-422-8274

U.S. fax number: 1-843-422-8274

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What You Need to Know	Interim Guidance
Vaccination Strategies	ACAM2000
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Related Resources

Vaccination Operational Planning Guide
FDA EUA Fact Sheet for Providers [900 KB, 16 pages]
FDA EUA Fact Sheet for Patients and Caregivers [465 KB, 5 pages]

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